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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738

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EXAMINER
AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
1772	

MAIL DATE	DELIVERY MODE
08/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,059	SCHOENLE ET AL.	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74,76-84,86-91 and 130-133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,76-84,86-91 and 130-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species (i) in the reply filed on May 17, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

2. Claims 74, 76-78 and 80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (USPN 6,110,142).

In regard to claim 74, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36, which is tube-shaped) of a medical device, where the component comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claim 80, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claim 76, Pinchuk et al. teach that the component is tube-shaped and a catheter (item 21, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36).

In regard to claims 77 and 81, Pinchuk et al. teach that the balloon can be coated with lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that the balloon comprises a first layer (the polyamide layer of Pinchuk et al.) and a second layer (the polyvinyl

pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layer necessarily have different flexibilities).

In regard to claims 78 and 82, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 22,500 psi.

3. Claims 84, 86, 88, 89, 91, 132 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (USPN 5,306,246).

In regard to claims 84 and 88, Sahatjian et al. teach a component (catheter including balloon, item 4, Fig. 2, item 4 shown but unlabeled in Fig. 1, which is tube-shaped) of a medical device (col. 2, lines 32-35), where the component comprises a polyamide having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18).

In regard to claim 86, Sahatjian et al. teach that the component is a catheter (col. 2, lines 32-35 and Fig. 1).

In regard to claims 89 and 91, Sahatjian et al. teach a tube-shaped portion (balloon, item 4, Fig. 2, shown but unlabeled in Fig. 1 and col. 2, lines 32-35 and 58-61) of a catheter (col. 2, lines 32-35) where the tube-shaped portion has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51).

In regard to claims 132 and 133, Sahatjian et al. teach that the material of the component includes a copolymer (col. 3, line 48-col. 4, line 6).

Claim Rejections - 35 USC § 103

4. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Sahatjian et al. (USPN 5,306,246).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed above. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21).

Pinchuk et al. fail to teach that the balloon has a hoop stress of at least about 3300 psi.

Sahatjian et al. teach a balloon (col. 2, lines 32-35) comprising polyamide (col. 3, lines 48-62) where the material comprising polyamide has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18). Therefore, one of ordinary skill in the art would have recognized to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

5. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. (USPN 5,306,246) in view of Pinchuk et al. (USPN 6,110,142).

Sahatjian et al. teach the balloon as discussed above. Sahatjian et al. teach that the balloon (col. 2, lines 32-35) comprises polyamide (col. 3, lines 48-62)

Sahatjian et al. fail to teach that the balloon comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

6. Claims 130 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Wang et al. (USPN 6,124,007).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed above. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21). PEBAX (polyether block amide) is listed in some of the titles of the publications listed in the "Other Publications" section of Pinchuk et al.

The text of the specification of Pinchuk et al. does not explicitly state any copolymers that are suitable as the material of the balloon of Pinchuk et al.

Wang et al. disclose that polyether block amide (and other copolymers) is a suitable material for use as a material of an angioplasty balloon (col. 4, line 33-col. 5, line 67). Therefore, one of ordinary skill in the art would have recognized to have used polyether block amide (or another of the other copolymers disclosed by Wang et al.) as a material of the balloon of Pinchuk et al. since polyether block amide (and the other copolymers disclosed by Wang et al.) are well known materials for use as a material of an angioplasty balloon as taught by Wang et al. (and as suggested by the fact that the polyether block amide is listed in some of the titles of the publications listed in the "Other Publications" section of Pinchuk et al. [which pertains to angioplasty balloons]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used polyether block amide (or another of the other copolymers disclosed by Wang et al.) as a material of the balloon of Pinchuk et al. since polyether block amide (and the other copolymers disclosed by Wang et al.) are well known materials for use as a material of an angioplasty balloon as taught by Wang et al. (and as suggested by the fact that the polyether block amide is listed in some of the titles of the publications listed in the "Other Publications" section of Pinchuk et al. [which pertains to angioplasty balloons]).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-

1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter B. Aughenbaugh
7/23/07

7/23/07